UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ASCENT PHARMACEUTICALS, INC., Plaintiff, v. U.S. DRUG ENFORCEMENT ADMINISTRATION Defendant.	Civ. No. 2:23-cv-07211 **COMPLAINT**

Plaintiff Ascent Pharmaceuticals, Inc. ("Ascent"), for its complaint against Defendant United States Drug Enforcement Administration ("DEA"), hereby alleges, based on knowledge of its own conduct, and on information and belief as to all other matters, as follows:

NATURE OF ACTION

1. Ascent, one of the nation's few minority-owned generic pharmaceutical companies, seeks the court's intervention to avert the shutdown of its company caused by DEA's failure to discharge its statutory duties.

2. For the past 12 years, Ascent, which is based in Central Islip, has steadily grown its business. By July 2022, Ascent had approximately 330 employees and manufactured more than 15 types of controlled substances.

3. Now, never having been the subject of prior regulatory sanctions, Ascent is on the verge of collapse because DEA has failed to act on its quota applications submitted for the 2023 Calendar Year (the "Quota Applications"). As described below, a quota application is a regulatory prerequisite to procuring controlled substances. Without an assigned quota from DEA for each drug it manufactures, a pharmaceutical manufacturer cannot operate.

4. As a result, Ascent's operations have nearly come to a grinding halt. DEA's inaction has devastated Ascent's business, causing a loss of 70% of projected revenues for 2023-2024. Ascent has also lost 30% of its workforce.

5. More importantly, DEA's inaction—as yet unexplained—prevents Ascent from making and delivering vital medications, including drugs necessary to treat both adults and children with Attention Deficit Hyperactivity Disorder ("ADHD").

6. Ascent's inability to supply ADHD medications is contributing to a national crisis, since ADHD drugs are already in short supply. Ascent supplied 20% of the market for generic ADHD medications nationwide. Turning off that supply is making a grave situation infinitely worse.

7. Earlier this month, 97% of independent pharmacy owners reported shortages of Adderall (a leading ADHD medication) and similar generic medications.[1] The scarcity of ADHD medications is causing a new public-health crisis.[2] For this reason, while Ascent has been urged by congresspeople and pharmaceutical providers to step up production of ADHD medications, its hands have been effectively tied by DEA.

8. For this reason, Ascent moves this Court for injunctive relief, compelling DEA to issue a decision on Ascent's applications to procure certain raw materials used to manufacture ADHD medications, as described below.

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[1] *See* Leah Kuntz, *The Rx Crisis: The Impact of Ongoing ADHD Medication Shortages* (Aug. 7, 2023), https://www.psychiatrictimes.com/view/the-rx-crisis-the-impact-of-ongoing-adhd.

[2] *See* Christina Caron, *The Collateral Damage of A.D.H.D. Drug Shortages* (Aug. 28, 2023), https://www.nytimes.com/2023/08/15/well/mind/adhd-adderall-shortage-children.html#:~:text=Because%20of%20the%20medication%20shortage,with%20multiple%20doctors%20and%20parents.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343(a)(4) over Plaintiff's federal claims.

10. Venue is properly laid in the Eastern District of New York because a substantial part of the events and omissions giving rise to the claims set forth herein occurred in this District.

PARTIES

11. Ascent is a minority-owned generic drug wholesale manufacturer incorporated in New York. Founded in 2011, Ascent develops and produces a range of specialty prescription drugs to treat medical conditions including ADHD, cardiovascular and inflammatory symptoms, depression, and pain. The company has invested more than $200 million in its facilities, good manufacturing practices, and research and development. Approximately 70% of its business concerns the production of Schedule II controlled drugs. The company is registered with DEA under numbers RA0448503 and RA0452095.

12. Defendant DEA is a federal government agency tasked with enforcing the controlled substances laws and regulations of the United States, and is headquartered in Virginia.

FACTUAL ALLEGATIONS

13. DEA regulates controlled substances through the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. § 801 *et seq.,* as well as regulations it promulgates.[3] The Attorney General has delegated his regulatory authority under CSA to the Administrator of DEA.

14. Pursuant to this authority, DEA has issued extensive regulations implementing the CSA, including 21 C.F.R. § 1303.12. This regulation requires the Administrator to fix and issue

[3] *See* 21 U.S.C. § 826; 28 C.F.R. § 0.100.

an individual quota to each registrant procuring Schedule I or II drugs who submits a yearly application. The quota authorizes the registrant to procure a specific quantity of raw materials for manufacturing during the next calendar year.

15. As a manufacturer of controlled substances, Ascent is required to register with DEA and maintain strict accounting for all distributions of Schedule I and II drugs.[4] To facilitate accounting and ensure the nation has a sufficient amount of each controlled substance in circulation, DEA enforces a quota system. This system simultaneously acts as a preventative measure against diversion by enabling DEA to limit the amount of drugs introduced into the supply chain.

16. Under the CSA, Ascent must apply for individual procurement quotas on or before April 1 of the year preceding the calendar year for which the quota is being applied.[5] For example, Ascent applies by April 1, 2022, for its 2023 quota. In turn, DEA must respond to qualified applicants on or before July 1 of the year of the application (so, DEA should decide on the 2023 quota by July of 2022).[6]

17. Because 70% of Ascent's business involves manufacturing Schedule II controlled drugs, Ascent—like all other manufacturers and distributors of controlled substances—relies on DEA's timely approval of its quota applications to fulfil its work mandate and supply medications pursuant to customer contracts.

18. Notwithstanding the July 1, 2022 statutory deadline for its decision, DEA has still not made a decision on the Quota Applications.

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[4] Joseph T. Rannazzisi, Mark W. Caverly, *Drug Enforcement Administration Practitioner's Manual*, U.S. Dep't of Just. Drug Enf. Admin. Office of Diversion Control (2006), https://www.in.gov/dhs/files/DEA_Practicioner_Manual.pdf.
[5] 21 C.F.R. § 1303.12(b).
[6] 21 C.F.R. § 1303.12(c).

A. Ascent's Business Operations

19. Upon receiving DEA's approval, Ascent acquires raw materials from several suppliers. Once Ascent produces the medications, it sells approximately 98% of its products to Camber Pharmaceuticals Inc. ("Camber"), a corporate affiliate with a common owner.

20. Camber does not take possession of any of the medications. Because it has no DEA registration, it uses a third-party agent, R&S Solutions, LLC (DEA Registration No. RR0519934),[7] to distribute Ascent's drugs to down-stream drug-distribution companies and national pharmacies, such as Walgreens and CVS, and independent pharmacy groups.

21. In this regard, Ascent's operations have not materially changed since it was founded in 2011.

B. Ascent's Quota Applications and the Ensuing Audits

22. In April and May 2022, Ascent submitted its Quota Applications for 11 different drugs for the 2023 Calendar Year. These applications included requests for quotas for Amphetamine (which are used to make generic Adderall) and Dexmethylphenidate, as well as Methylphenidate and Lisdexamfetamine (which are also prescribed to treat, among other things, ADHD). These quotas were necessary to continue the supply of ADHD medications.

23. Although Ascent's applications were slightly late, DEA regularly processes and approves applications submitted after April 1. Moreover, DEA never objected to receiving Ascent's applications late and never raised this as a ground for delaying action on those applications.

24. But, Ascent's Quota Applications were delayed nonetheless.

[7] R&S Solutions, LLC is a Tennessee corporation located at 96 American Drive, Suite 100A, Jackson, Tennessee 38301.

25. Since May 3, 2022, DEA has conducted an extended series of audits of Ascent. These have included a regulatory audit, an accountability audit, and a compliance audit. During these various audits, DEA has purported to find discrepancies in some of Ascent's recordkeeping and inventory.

26. Ascent has fully cooperated with these audits. When faced with purported discrepancies, Ascent has provided additional documentation to clarify the purported discrepancies.

27. To be sure, some errors were noted. For example, the review uncovered that an employee filled out an inventory control form failed to add a column correctly. Ascent conceded the error. (*See* Walden Decl., Ex. 3.) Other discrepancies were clarified when Ascent provided additional documents, such as batch records.

28. During this long process, DEA has gotten far into the weeds, as it should. It has visited Ascent repeatedly to follow-up on requests. It has made more than 10 requests for additional documentation. All along, Ascent cooperated. To this day, DEA has never issued any findings of regulatory violations.

29. During this process, Ascent repeatedly asked for explanations and urged DEA to speed up its process. This included direct entreaties from Ascent CEO, Dr. Sudhakar Vidiyala, who wrote on October 26, 2022: "**I have been requesting a call or an in person meeting to go over the issues, but unfortunately you never responded to those requests. Please call me or arrange [an] in person meeting to resolve the issues. I appreciate your prompt response [to] my request."** DEA responded by saying it still sought unspecified information, and mechanically reciting that Ascent's Quota Applications were **"under review at this time.**"

30. To better facilitate its cooperation and manage communications with DEA, Ascent hired regulatory counsel on November 1, 2022. Counsel submitted a detailed letter and well-organized documents explaining the purported discrepancies.

31. Without any meaningful update or information from the DEA Field Office, Ascent's new counsel wrote DEA's Principal Deputy Administrator ("PDA") on November 7, 2022. In the letter, counsel advised the PDA of the background and history of DEA's audits and Ascent's clarifying responses. Counsel described the lack of any meaningful information coming from the Field Office, saying "**we [Ascent] remain unclear regarding what relationship the Quota Application has to the regulatory inspection**." Counsel asked to meet with the PDA to try to resolve any outstanding issues. The PDA did not respond.

32. Instead, DEA sent a letter to Ascent on November 11, 2022, **"extending an invitation"** for Ascent to clarify certain discrepancies revealed by the audits. (Walden Decl. Ex. 1.)

33. On November 22, 2022, Ascent timely responded with a detailed production clarifying the alleged discrepancies, which included supporting documents.

34. Not receiving a response, Ascent followed-up with DEA. Thereafter, it became clear that DEA somehow misplaced Ascent's production.

35. After Ascent helped DEA find the production, DEA responded with **"[t]his is helpful."**

a) In its detailed, 24-page response, Ascent explained each alleged discrepancy, and provided supporting documentation to DEA. Krista Tongring, a nationally respected DEA consultant, who spent more than 20 years in government service, including over 13 years at the U.S. Department of Justice as a federal prosecutor

and over six years at DEA as a senior attorney for the Diversion and Regulatory Litigation Section and as the Acting Section Chief in the Office of Compliance, has explained two examples that bear this out.

b) For example, DEA claimed that its accountability audit of methylphenidate 20mg (packaging stage of manufacturing) showed that there was an overage of 4,413,600 tablets (meaning Ascent had roughly four million more tablets than its inventory records provided). (Walden Decl. Ex. 1.) In its response, Ascent explained—and Ms. Tongring has confirmed—that DEA simply relied on incorrect inventory records. Ascent provided DEA with the relevant records to correct its accountability audit consistent with this explanation, as Ms. Tongring also confirmed.

c) As another example, DEA claimed that there was a discrepancy of -56.7978 kg (-4.83%) of oxycodone 15 mg and oxycodone 30 mg (blend stage of manufacturing). (*Id.*) Ascent responded and explained that DEA did not take into account the acceptable non-recoverable loss that occurs during the manufacturing process – particularly during the mixing/blending stages of manufacturing. Ascent provided the batch records to establish that all of the batches during the blend stage of manufacturing for oxycodone 15 mg and oxycodone 30 mg were within the acceptable limits for non-recoverable losses. Ascent also provided a reconciliation based on these records showing that there was no discrepancy as DEA had claimed.

36. Having demonstrated DEA's errors, Ascent's counsel followed up with DEA repeatedly over the next two weeks, urging DEA to resolve the Quota Applications.

37. Finally, on December 8, 2022, DEA responded, saying that DEA "appreciate[s] your concern regarding time." (Walden Decl., Ex. 2.) However, DEA complained that reviewing Ascent's productions was a "laborious task." Remarkably, DEA blamed Ascent for taking too long producing documents (this was false, as noted above and throughout). (*Id.*)

38. Ascent followed-up again on December 16, after which DEA sent yet another communication with an assortment of complaints about minor discrepancies between various documents Ascent had provided in the November 22 production. (*Id.*) These new "concerns" included a slight divergence between a hand-written document and a typed one. (*Id.*) As with the other "discrepancies," Ascent's counsel responded quickly, sending a letter on December 20, 2022, with clarifying explanations.

39. This pattern—DEA finding minor discrepancies, and Ascent clarifying or correcting DEA's misunderstandings—continued through the first quarter of 2023. Throughout, Ascent continued to implore DEA to decide the Quota Applications, which had nothing to do with—what seemed to be—DEA searching for some basis to take adverse action against Ascent. Nevertheless, Ascent's counsel sent timely and complete responses to all of DEA questions.[8] Tellingly, DEA never issued any finding of a regulatory violation.

40. But nor did DEA decide the Quota Applications.

41. All the while, the ADHD crisis became more acute, and the harm to Ascent's business became more grave.

[8] Attached as Exhibits 4-7 are additional communications from DEA to Ascent regarding the Quota Applications.

42. Frustrated with the extreme delay, the impact on its business, and the impact on patients, Ascent's CEO sent a letter to the Senate Judiciary Committee on March 23, 2023, asking it to investigate DEA's inaction in light of the scarcity of ADHD medications.

43. Thereafter, DEA seemed to turn a corner, writing Ascent to acknowledge receipt of more clarifying documents, and further acknowledging that additional document requests would unduly "burden" Ascent and likely result in "duplicative production."

44. Nevertheless, DEA's inaction continued. Despite the above acknowledgment, more document requests came on June 2023.

45. Concerned about the critical shortage of ADHD medications in the market, Ascent's counsel called DEA and asked for an "interim" quota to help mitigate the patient impact of Adderall scarcity. Although expressing "openness" to the idea, DEA never responded with a decision.

46. Instead, DEA issued a subpoena on June 23, 2023 for any and all communications between Ascent and its primary customer, Camber, for a two-year period. Ascent responded within five days, fully complying with the subpoena.

47. Approximately two weeks later, on July 11, 2023, DEA issued two additional subpoenas, this time for records Ascent had already largely provided during the various "audits."

48. During this entire period, counsel for Ascent asked repeatedly for meeting and information from DEA—most urgently, details on what specifically was causing the delay of DEA's now long-overdue quota decision.

49. DEA refused to meet with Ascent's counsel. When counsel made urgent entreaties as the business realities for Ascent became grimmer, DEA responded to Ascent's requests with "received."

50. With no other options, and not wanting to sue its primary regulator, Ascent's counsel wrote DEA Administrator Anne Milgram on August 3, 2023, begging for information or a decision on the 2023 quotas.

51. No response was forthcoming.

52. Still, committed to trying to find a way to satisfy DEA, but running out of all but a few categories of raw materials, Ascent hired a former DEA diversion consultant from one of the nation's premier consulting firms, Guidepost Solutions, to further facilitate Ascent's cooperation and bring the quota decision to a close.

53. That consultant, Ms. Tongring, tried on multiple occasions to contact DEA (via telephone and email) to clarify any further purported discrepancies, with which she disagreed. Despite speaking with DEA twice on the phone, DEA provided no substantive information to her in response to her inquiries.

54. With no option other than to sue DEA, Ascent tried one last show of good faith: it directed Guidepost to conduct its own inspection of Ascent's facilities.

55. Guidepost conducted that inspection on September 13 and 14—and emailed a voluntary report to DEA on September 15, 2023.

56. Among other findings, Guidepost found that Ascent's recordkeeping "appear[s] to be in compliance with DEA laws and regulations." And, based on Guidepost's assessments, it reiterated that some of the previously identified discrepancies were based on DEA's own misunderstandings. Guidepost punctuated the remark by saying, "**this is a vital point to consider**."

57. Again, DEA did not respond.

58. With no other options, Ascent commences this action.

59. To this day, DEA has never made a finding that Ascent violated any DEA law or regulation.

60. It is highly unusual for DEA not to respond to a procurement quota application for this length of time.

C. DEA's Inaction's Contributes to a New Public Health Crisis

61. DEA's failure to respond to Ascent's Quota Applications (for Dexmethylphenidate; Lisdexamfetamine; Methylphenidate; D,L Amphetamine; and D-Amphetamine) which can be used to make eight different ADHD medications, including generic versions of Concerta, Ritalin, Adderall, Vyvanse, and Methylin, affects not only the company, but also U.S. patients' ability to obtain necessary medications. As has been widely reported, there is a nationwide shortage of medications to treat ADHD.[9] DEA has been widely criticized for failing to address the problem.[10]

62. In October 2022—as DEA prevented Ascent from manufacturing amphetamines and treatments for ADHD—the U.S. Food and Drug Administration ("FDA") acknowledged a nationwide shortage of Adderall.[11] The bottleneck of brand name and generic-

[9] *See* Leah Kuntz, *The RX Crisis: The Impact of Ongoing ADHD Medication Shortages*, Psychiatric Times (Aug 7, 2023), https://www.psychiatrictimes.com/view/the-rx-crisis-the-impact-of-ongoing-adhd (citing a report that 97% of independent pharmacy owners reported shortages of Adderall in early 2023).

[10] *See, e.g.*, Joe Lancaster *Short on Adderall? Blame DEA Production Caps*, Reason.com (April 2023) https://reason.com/2023/03/14/wheres-your-adderall/ ("But even after the FDA reported a shortage, the DEA kept the 2022 levels intact in its 2023 quotas for Adderall's ingredients: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate.").

[11] *See*, *FDA Announces Shortage of Adderall*, U.S. Food & Drug Administration (Aug. 1, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall.
See also, Christina Jewett, *F.D.A. Confirms Widespread Shortages of Adderall,* The New York Times (Oct. 13, 2022), https://www.nytimes.com/2022/10/13/health/adderall-shortage-adhd.html.

equivalent prescriptions has been linked to depression, withdrawal, and declines in learning and self-esteem.[12]

63. On September 22, 2022, a Senior Regulatory Review Officer at FDA sent an email to Ascent indicating that FDA had received reports from doctors and patients regarding a shortage of certain ADHD medications. FDA asked whether Ascent had any supply of the products available. Ascent replied that it did not due to DEA's failure to issue a decision on its Quota Applications, and requested that FDA inform DEA of the problem. On September 29, 2022, FDA emailed Ascent stating that it had relayed Ascent's concerns regarding the Quota Applications to DEA. On July 18, 2023 and August 28, 2023, FDA again sent an email to Ascent regarding reports of shortages of additional ADHD medications. Ascent again responded that they did not due to DEA's failure to issue a decision on its Quota Applications.

64. The shortage has not escaped the notice of Congress. Members of Congress have called on FDA and DEA, urging both agencies to act on the continued shortage of Adderall and generic ADHD medications; Rep. Abigail Spanberger sent a letter to the agencies on December 20, 2022, and Sen. Ron Wyden sent a letter on June 5, 2023. In response, FDA attributed the shortage to the "substantial increase in prescribing, while simultaneously stating **supply has not been able to keep up with demand."**[13]

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[12] *See* Dani Blum, *Amid the Adderall Shortage, People With A.D.H.D. Face Withdrawal and Despair*, The N.Y. Times (Nov. 16, 2022), https://www.nytimes.com/2022/11/16/well/mind/adderall-shortage-withdrawal-symptoms-adhd.html.

[13] *See* Letter from Robert M. Califf, M.D., Comm'r of Food and Drugs, U.S. Food and Drug Admin., to Sen. Ron Wyden (Aug. 1, 2023) (available at https://www.wyden.senate.gov/imo/media/doc/fda_response_senator_ron_wyden_adhd_drug_shortages.pdf) (emphasis added).

65. The Offices of Senator Sheldon Whitehouse and Senator Ron Wyden reached out to Ascent directly on May 18, 2023 and August 18, 2023, to inquire what Ascent could do about the shortage. However, Ascent's hands were tied due to DEA's inertia.

66. Ironically, in August 2023, the leadership of DEA and FDA co-authored a letter where they called on drug manufacturers to make more Adderall.[14] All the while, Ascent—who previously made up 20% of the market for generic ADHD medications—stands by unable to assist with production due to DEA's continued delay without any explanation.

67. But it should come as no surprise that DEA's rigid procurement quotas for amphetamines arrives on the heels of opioid-crisis-era investigations. DEA's response—which reflects a drug policy that is focused on controlling supply—is a clear and ill-conceived overcorrection and reaction to criticism it received for mishandling of opioid abuse.[15]

68. Amidst this year-long deficiency, multiple distributors, such as CVS, Walgreens, and Walmart, have contacted Camber seeking its products and citing the public need for its medication. Ascent, however, has made a dramatic reduction in manufacturing of ADHD stimulant medications due to the quota application issue. As Ascent awaits DEA approval on the Quota Applications, it remains unable to respond to the demands of patients, pharmacies, and the public.

69. Ascent could help alleviate the shortage if DEA approves its Quota Applications for raw materials that are used to create ADHD medications: Dexmethylphenidate; Lisdexamfetamine; Methylphenidate; D,L Amphetamine; and D-Amphetamine.

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[14] *See* Sarah Braner, *FDA, DEA Urge Drug Companies To Make More Adderall*, The Messenger (Aug. 2, 2023 02:36 PM ET) https://themessenger.com/health/us-health-authorities-urge-drugmakers-to-boost-stimulant-production.

[15] *See, generally,* OIG Report, Oct. 1, 2019 (criticizing DEA's enforcement of suspicious order regulations and ability to detect diversion of pharmaceutical opioids) https://oig.justice.gov/reports/2019/e1905.pdf.

D. DEA's Inaction Harms Ascent and its Employees

70. Since 2022, Ascent has kept DEA apprised of the adverse effects the application delay has had—and continues to have—on the company.

71. Today, as a result of the quota delay, Ascent's operations have come to a near halt and its business has been devastated. Specifically, Ascent has:

- Lost 70% of its projected revenues, totaling a monthly loss of approximately $8 million to $10 million;
- Incurred damage to its reputation among customers and industry;
- Is in danger of breaching financial covenants with banks and lost contracts due to its substantial revenue loss;
- As of June 2023, seen a reduction of approximately 100 employees
- For the employees who remain, the obstacles to production have resulted in fewer available shifts, less overtime, and fewer raises and bonuses. Moreover, Ascent had committed to local Industrial Development Agency to create at least 100 new jobs in reliance on its projected business growth. Now, it cannot accomplish this goal; and
- Delayed all new R&D launches due to a lack of raw material quota, causing millions of dollars of lost investments. Ascent had invested over $200 million to set up its business, R&D, and infrastructure.
- In addition, Ascent's sister company, Camber, has incurred penalties ranging from $6 million to $8 million for failing to supply Ascent's products under its customer contracts.

72. DEA's continued inaction will only increasingly be felt. More Ascent employees will lose their jobs. Business relationships developed over a decade will abruptly end. And Ascent will be forced to shutter.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Violation of the Administrative Procedure Act ("APA")
5 U.S.C. § 555 et seq. and § 706 et seq.

73. Ascent repeats and realleges the foregoing allegations as if fully set forth herein.

74. DEA is an agency within the meaning of the APA. 5 U.S.C. § 551(1).

75. Pursuant to 5 U.S.C. § 555(b), DEA has an obligation to conclude matters presented to it "within a reasonable time."

76. The APA empowers courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

77. Between April 7, 2022 and May 25, 2022, Ascent submitted procurement quota applications to DEA to obtain quotas for the calendar year 2023.

78. Pursuant to 21 C.F.R. § 1303.12(c), DEA was required to respond to Ascent's procurement quota applications on or before July 1, 2022.

79. 21 C.F.R. § 1303.12(c) provides: "The Administrator shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use (1) [a]ll quantities of such class necessary to manufacture all quantities of other basic classes of controlled substances listed in Schedules I and II which the applicant is authorized to manufacture pursuant to § 1303.23; and (2) [s]uch other quantities of such class as the applicant has applied to procure and use and are

consistent with his past use, his estimated needs, and the total quantity of such class that will be produced."

80. DEA has not provided a response or issued a determination with respect to Ascent's procurement quota applications.

81. The deadline for DEA to have responded or issued a determination was over 14 months ago.

82. DEA has unlawfully withheld and unreasonably delayed in providing a response to the Quota Applications.

SECOND CAUSE OF ACTION

Mandamus pursuant to 28 U.S.C. § 1361

83. Ascent repeats and realleges the foregoing allegations as if fully set forth herein.

84. The Mandamus Act grants district courts original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the Plaintiff. 28 U.S.C. § 1361.

85. Ascent seeks relief in the nature of mandamus, in that it requests a mandatory preliminary injunction to compel DEA to issue a decision on its quota applications, submitted between April 7, 2022 and May 25, 2022.

86. Such relief is a positive command, plainly described, and free from doubt.

87. Pursuant to 21 C.F.R. § 1303.12(c), DEA has a plainly defined and peremptory duty to have responded to Ascent's procurement quota applications on or before July 1, 2022.

88. DEA has not provided a response or issued a determination with respect to Ascent's procurement quota applications, to which Ascent has a clear right.

89. The deadline for DEA to have responded or issued a determination was over 14 months ago.

90. Ascent has exhausted all administrative remedies and no adequate remedy exists.

91. As a result of DEA's inaction, Ascent has suffered and continues to suffer irreparable harm entitling it to relief.

PRAYER FOR RELIEF

Wherefore, Ascent requests judgment in its favor as follows:

(a) Granting preliminary injunctive relief pursuant to Fed. R. Civ. P. 65 compelling DEA to respond, to Ascent's applications for quotas for Dexmethylphenidate; Lisdexamfetamine; Methylphenidate; D,L Amphetamine; and D-Amphetamine, within seven (7) days of execution of the Court's Order;

(b) Granting permanent injunctive relief pursuant to Fed. R. Civ. P. 65 compelling DEA to respond to the Quota Applications; and

(c) Awarding such other relief as deemed just and appropriate.

Dated: New York, New York
September 27, 2023

Respectfully submitted,

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